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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,406	07/19/2001	Yoshihiro Sokawa	55600-8004.US00	9683

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EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,406

Applicant(s)

SOKAWA ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/21/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-21 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Double Patenting

Claim 21 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending Application No. 10/698,927. Applicant's intent to address this rejection after indication of allowable subject matter in one application is noted; the rejection is restated to indicate it has not been withdrawn.

Claim Rejections - 35 USC § 112

Claims 18-21, 23-26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record. Applicant states that an increase in OAS levels and a decrease in ALT is shown throughout tables 3-6, with a general trend showing increase in OAS coincident with a drop in HCV and ALT over the course of treatment. The examiner does not agree with this characterization of the data. Patient MSM002 does show both a general increase in OAS and a general decrease in ALT over the course of treatment, with little improvement in HCV load. Patient AMC007 shows a general increase in OAS and a transient decrease in HCV load, with little improvement in ALT. Patient DBF012 shows an increase in OAS with little or no change in viral load or ALT. Other patients in the study show fluctuations in viral load or ALT at different times from fluctuations in OAS (e.g. PAB001, JRJ006, ALW008). There are no control data to indicate the extent of variation in these measurements in the absence of treatment. Although it is recognized in the HCV art that there are nonresponders to any treatment and that treatments often

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lose efficacy over a long term, one skilled in the art is unlikely to be convinced of the efficacy of this treatment when only 3 patients show consistent elevation of OAS, and the clinical response in each patient is different (e.g. reduced HCV in DBF012, reduced ALT in AMC007, little or no change in DBF012). Therefore the arguments are unconvincing and the rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 18-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soos et al 6,372,206, for reasons of record. The claims have been amended to recite a daily dosage between 10^8 - 10^{10} units; this includes the "about 1×10^8 units per day" specifically suggested by Soos. Furthermore, Soos teaches that IFN-tau is "without the toxic effects that are usually associated with IFNs." Applicant argues that Soos does not teach that the amount of interferon-tau must be sufficient to raise bloodstream levels of OAS. However, if the therapeutic effect of IFN-tau is mediated by elevated OAS, then following the suggestions of Soos to use "a therapeutically effective amount" would necessarily involve an amount sufficient to elevate OAS. Therefore it is maintained that the invention as a whole is prima facie obvious.

Kondili et al (Journal of Viral Hepatitis 7:184-195, 2000) is cited as of interest as a contemporary review of HCV therapy clinical trial design. Arase et al (Journal of Gastroenterology 35:221-225, 2000) is cited as of interest as documenting fluctuating viral load in chronic HCV patients.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/31/04


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-1600